

Vivity Extended Vision IOL: Expanding Patient Selection for Premium Lens Options



Offering a variety of patient-centric procedures can delight patients and enhance patient management.

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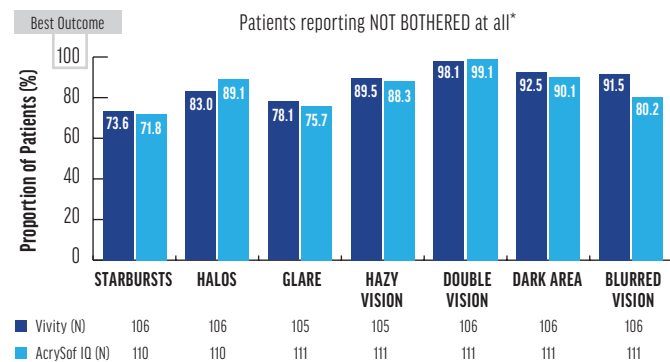
INTRODUCTION

As individuals work longer and maintain active lifestyles, presbyopia correction at the time of cataract surgery is becoming a more popular and common request from today's cataract patients. Historically, surgeons have used intraocular lenses (IOLs) with a diffractive optical design, including multifocal and diffractive extended depth of focus (EDOF) IOLs, in addition to traditional monofocal IOLs targeted for monovision to help mitigate the effects of presbyopia. The AcrySof PanOptix trifocal IOL (Alcon) is the latest advancement in diffractive IOL technology shown to provide excellent vision from distance to near. Recently, a novel non-diffractive, extended range of vision IOL, AcrySof IQ Vivity (Alcon), has been added to the refractive cataract surgery armamentarium. How does this novel non-diffractive EDOF IOL technology fit in the presbyopia-mitigating IOL landscape?

HOW DOES THE ACRYSOF IQ VIVITY IOL STAND APART FROM DIFFRACTIVE IOLS?

Cathleen M. McCabe, MD: The Vivity IOL is a unique non-diffractive IOL that uses the novel X-WAVE technology (Alcon) to provide excellent distance and intermediate vision with good functional near vision in both bright and dim light conditions.¹ As an investigator in the Vivity IOL clinical registration trial, I observed that patients with Vivity reported very low levels of glare, halos, and starbursts. These are also the most commonly noted complaints in patients who have diffractive IOLs. However, study patients who received the Vivity lens reported visual disturbances at levels not significantly different than an advanced monofocal IOL¹ (Figure 1), unlike what is seen with diffractive IOLs where visual disturbance rates are significantly worse than monofocal IOLs.^{1,2} In fact, patient-reported visual disturbances, evaluated in two separate large scale registration studies using two different validated questionnaires, demonstrated comparable percentages of patients that reported not being bothered at all by visual disturbances from Vivity and the control AcrySof IQ monofocal IOL.^{1,3} This is a major advancement addressing an important limitation of most other presbyopia-mitigating IOL technology.

Shamik Bafna, MD: In the US registration study, the Vivity IOL provided a continuous extended range of vision better than 20/25 from distance to intermediate as demonstrated by both the binocular defocus curve and binocular corrected and uncorrected visual acuities. At the same time, Vivity IOL also delivered binocular



*Patients reporting "Not Bothered At All" includes patients who did not experience the disturbance and those reporting "Not At All Bothered".

Figure 1. Patient reported visual disturbances (not bothered) in the US registration study. Safety analysis set, 6 months.

near visual acuity (~20/32).¹ In my experience, I have found that the majority of cataract patients implanted with the Vivity IOL have been extremely pleased with the quality and range of vision extending from distance to intermediate vision. They were also satisfied with their functional near vision.

WHAT PATIENT CHARACTERISTICS ARE IDEAL FOR IMPLANTING THE EXTENDED VISION IOL?

Dr. McCabe: Based on the novel non-diffractive optical design of the lens, the Vivity IOL is my IOL of choice for most cataract patients that want good intermediate and functional near vision without high expectations for complete spectacle independence. It is an excellent choice for those patients demanding some near vision performance, but where potential visual disturbances associated more commonly with diffractive optics are a concern. The clinically proven monofocal-like visual disturbance profile decreases concern that complaints of glare, halos, or starbursts will result in unhappy patients.

Dr. Bafna: Although many presbyopia-mitigating IOLs have been introduced to the market over the past two decades, the most commonly used method to alleviate presbyopia at the time of cataract surgery is still monovision with monofocal IOLs. This methodology is chosen to avoid the potential concern of residual refractive error and reduced quality of vision related to the multifocal, trifocal, and diffractive EDOF IOLs. Our recent real-world evidence study using the American Academy of Ophthalmology IRIS Registry found that the

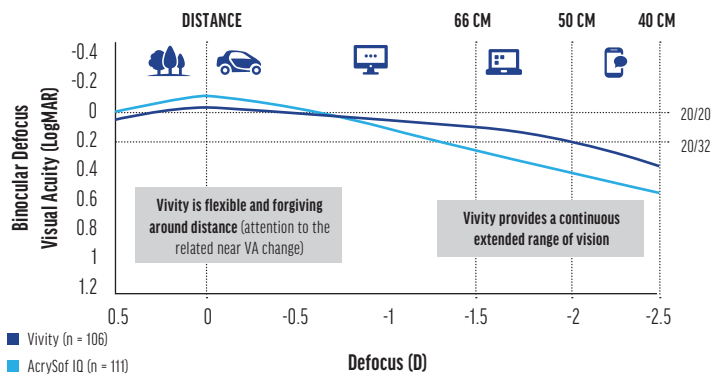


Figure 2. Vivity IOL Binocular Defocus Curve (US Registration Study).

majority of monovision patients (58.1%, n = 952) had a myopic offset less than or equal to -1.50 D.⁴ I believe these patients are highly motivated to have spectacle independence from distance to intermediate and are satisfied with functional near vision where they occasionally use spectacles for extended near tasks. The range of vision possible with the most common monofocal monovision approach can be easily achieved with the Vivity IOL targeted for bilateral emmetropia while still providing monofocal-like low visual disturbances.¹ There is no longer an optical rationale to intentionally leave a patient with compromised distance vision in one eye. Furthermore, patients won't be required to have previous monovision experience or have to trial contact lens monovision before the surgery. There is also no need to wait for first eye outcomes to then plan the second eye surgery, nor do we have to deal with post-operative adaptation to monovision. Additionally, in comparison to monovision which leaves only two distinct focal points of clarity, the Vivity IOL allows an extended range of clear vision over multiple focal points. The Vivity IOL allows me access to an entirely new population of patients seeking a better range of vision that I may have otherwise managed with monofocal monovision.

Dr. McCabe: Dr. Bafna just mentioned one concern that has discouraged some surgeons from offering presbyopia-mitigating IOLs, and that is the need to manage potential residual refractive error. The Vivity IOL has a flat defocus curve, especially around distance, which provides some level of forgiveness in hitting the refractive target while maintaining good distance visual acuity (Figure 2).¹

WHAT PATIENT CHARACTERISTICS SHOULD BE AVOIDED AND WHAT ARE GENERAL EXCLUSION CRITERIA?

Dr. McCabe: All patients in the Vivity registration studies had bilateral implantation targeting for emmetropia. The data suggest that patients with a strong desire for spectacle independence, including those spending extensive time doing near vision, are not ideal candidates for this lens. Instead, an IOL like the PanOptix Trifocal would

be my recommendation to provide increased spectacle independence and excellent near vision performance. PanOptix has been clinically proven to provide continuous range of vision with the possibility of 20/20 at distance, intermediate, and near.^{*†‡5}

WOULD YOU CONSIDER USING VIVITY IN PATIENTS WITH A NON-PRISTINE EYE?

Dr. Bafna: This lens has only been available for about one year in the earliest launched countries. There were no contraindications identified in the US registration study, but there is currently no published clinical data on non-pristine eyes, such as eyes with corneal refractive surgery history, glaucoma, or retinal pathology. Based on its unique non-diffractive design, extended range of vision, and monofocal-like visual disturbances profile, many surgeons including myself are interested in exploring its potential in a broader patient population. Additional clinical data will likely be published soon to provide further guidance on how to best use this IOL in different patient populations.

Dr. McCabe: Additionally, it is important to educate patients about ocular surface disease and manage dry eye before and after any cataract surgery to enhance long-term patient satisfaction regardless of the type of IOL.

SUMMARY

The AcrySof IQ Vivity EDOF IOL uses the novel non-diffractive X-Wave technology to enable patients to see well at distance and intermediate and provides functional near vision while maintaining a monofocal-like visual disturbance profile. Unlike previous EDOF IOLs, Vivity isn't limited by the compromises presented by diffractive optics. We believe it will effectively enable more surgeons to manage presbyopia in a greater number of cataract patients. ■

1. AcrySof® IQ Vivity DFU.
2. Tecnis Symfony DFU.
3. McCabe C, Berdahl J, Poyales F, et al. Visual Disturbance Profile of a Non-Diffractive Extended Vision Intraocular Lens from Two Pivotal Trials. Presented at: ESCRS, Sept. 2019, Paris, France.
4. Bafna S, Gu X, Merchea M. Incidence & Frequency Distribution of Monovision with Monofocal IOLs - An Analysis of the AAO Clinical Registry. Presented at: AAO Virtual Meeting, November 2020.
5. AcrySof® IQ PanOptix® DFU.

*Based on mean value of binocular defocus curve at near, intermediate, and distance at 6 months (n = 127).
†Snellen VA was converted from logMAR VA. A Snellen notation of 20/20² or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.

AcrySof® IQ Vivity™ Family of Extended Vision IOLs IMPORTANT PRODUCT INFORMATION

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS: The AcrySof® IQ Vivity™ Extended Vision IOLs include AcrySof® IQ Vivity™ and AcrySof® IQ Vivity™ Toric IOLs and are indicated for primary implantation for the visual correction of aphakia in adult patients with <1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof® IQ Vivity™ IOL is intended for capsular bag placement only. In addition, the AcrySof® IQ Vivity™ Toric IOL is indicated for the reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism.

WARNINGS/PRECAUTIONS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. This lens should not be implanted if the posterior

capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. Most patients implanted with the AcrySof® IQ Vivity™ IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the AcrySof® IQ Vivity™ IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic. It is possible to experience very bothersome visual disturbances, significant enough that the patient could request explant of the IOL. In the AcrySof® IQ Vivity™ IOL clinical study, 1% to 2% of AcrySof® IQ Vivity™ IOL patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ Vivity™ IOLs.

ATTENTION: Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.

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